

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 September 2001 (27.09.2001)

PCT

(10) International Publication Number
WO 01/70319 A2

(51) International Patent Classification⁷: A61M 15/00

11309 Derby Lane, Raleigh, NC 27613 (US). WAKE-
FIELD, Keith; 297A Winston Road, Clayton, NC 27520
(US).

(21) International Application Number: PCT/US01/07202

(22) International Filing Date: 7 March 2001 (07.03.2001)

(74) Agents: SANTUCCI, Ronald, R. et al.; Pitney, Hardin,
Kipp & Szuch, LLP, 20th Floor, 711 Third Avenue, New
York, NY 10017 (US).

(25) Filing Language: English

(81) Designated States (*national*): AU, CA, JP.

(26) Publication Language: English

(84) Designated States (*regional*): European patent (AT, BE,
CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC,
NL, PT, SE, TR).

(30) Priority Data:
09/531,732 21 March 2000 (21.03.2000) US

Published:

— without international search report and to be republished
upon receipt of that report

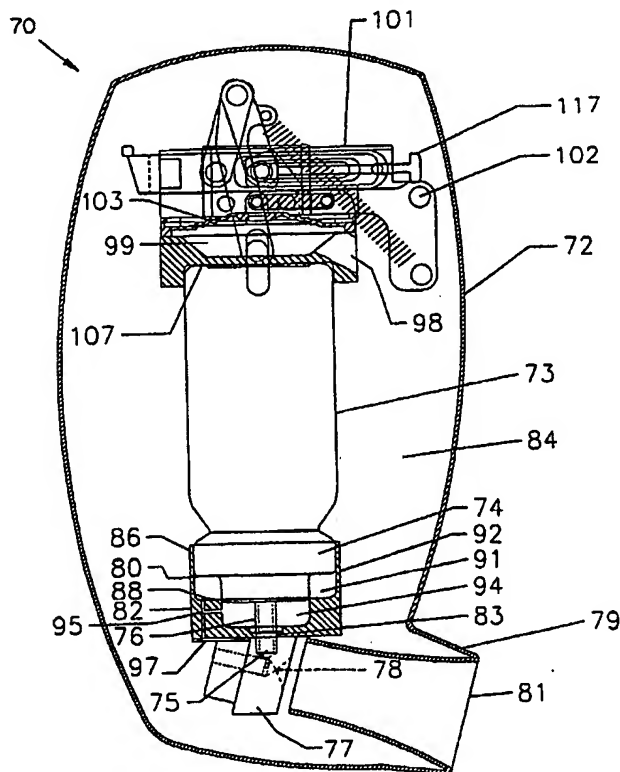
(71) Applicant: IEP PHARMACEUTICAL DEVICES,
INC. [US/US]; 6320 Angus Drive, Raleigh, NC 27617
(US).

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(72) Inventors: GENOVA, Perry, A.; P.O. Box 16036, Chapel
Hill, NC 27516 (US). WILLIAMS, Robert, C., III;

(54) Title: AN INHALATION ACTUATED DEVICE

(57) Abstract: An inhalation activated device or dispenser is disclosed. In particular, the dispenser comprises a housing for containing an aerosol canister containing a medication wherein the canister is moveably contained in the housing upon inhalation by the patient whereby a metered dose of a spray is initiated and a controlled period of time is established by a dwell means.



WO 01/70319 A2

AN INHALATION ACTUATED DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 This invention relates to a breath-actuated device. In particular, the device is directed to what is typically referred to as an inhaler having an aerosol medication containing canister, which upon actuation releases a metered dose of medication to a patient.

10 2. Description of the Prior Art

There are a variety of inhalation devices which release aerosol medication, in a continuous spray or in a metered dose or predetermined amount of medication, directly into the patient's mouth, nasal area or respiratory airways. Typically, these devices are actuated by the pressured actuation of the user's fingers, button action, or other related manual techniques. Although some are activated by the inhaling action of the users, heretofore there are few simple, inexpensive and reliable breath actuated devices developed.

Metered dose aerosol canisters of the medicine to be inhaled into the mouth, nasal areas or respiratory airways are manufactured by a variety of pharmaceutical companies. Metered dose aerosols are much the same as non-metered aerosol except that when the valve is depressed, a continuous spray does not result but instead a predetermined measured spray releases delivering a fixed amount of medication. Examples of such metered dose

25
30

inhalers are set forth in U.S. Patent Nos.
5,544,647, issued August 13, 1996 entitled "Metered
Dose Inhaler"; and 5,622,163 issued April 22, 1997
entitled "Counter for Fluid Dispensers"; and U.S.
5 Patent Application Serial Number 09/241,010 filed
February 1, 1999 entitled "Metered Dose Inhaler
Agitator" (commonly assigned), the disclosures of
which are incorporated herein by reference.
Devices of this type have proven to be very
10 satisfactory, however, as with everything else,
improved operation is desirable.

Aerosols used with manually actuated inhaler
devices often incorporate ambient air with the
volume of medication permitting a complete breath
15 of air by the patient while inhaling the
medication. Alternatively, aerosol medicines are
also available in continuous spray, which
continually spray as long as the valve or nozzle
pin is depressed.

20 Proper use of these manual actuated devices
requires that the spray be activated at the
beginning of the inspiratory cycle, so that the
medication is carried into the lungs rather than
being deposited in the mouth or throat. If this
25 actuation is not correctly coordinated with the
inspiratory phase the metered dose may be deposited
differently with each actuation and potentially
compromise the therapeutics and safety of the
product. A breath actuated device helps eliminate
30 this problem by making the product easier to

coordinate and more patient friendly, with predictable delivery and dispersion in the respiratory airways.

5 There are numerous factors leading to poor coordination ranging from the user's inherent skills, associated with the geriatrics and pediatrics to patients with impaired physical facilities. Recognizing the need for correct and accurately delivered doses in the asthmatics, COPD
10 patients and, as with other patients with other respiratory illnesses, a reliable breath activated device would improve the quality of life for these respiratory ill patients.

Summary of the Invention

15 The present invention comprises a metered dose dispenser for aerosol medication contained in a housing having a mouthpiece for insertion into a patient's mouth. A mechanical actuator mechanism is provided in cooperation with the canister, in
20 its initial locked position, which upon inhalation by a patient causes the canister to dispense a metered dose of medication as a spray from the mouthpiece to the patient. The dose is established by a metering valve associated with the canister.
25 A dwell means is provided which ensures complete discharge of the metered dose and subsequently, complete filling of the metering valve with the next dose after the dispensing.

Brief Description of the Drawings

Figure 1A is a partial side cross-sectional view of the metered dose inhaler in its locked or cocked state prior to inhalation;

5 Figure 1B is a partial side sectional view of an alternative embodiment of the inhaler shown in Figure 1A;

10 Figure 1C is a somewhat enlarged partial side sectional view of the medication canister and dwell chamber of embodiment 1B in its up (not dwelled) position;

15 Figure 1D is a somewhat enlarged partial side sectional view of the medication canister and dwell chamber of embodiment 1B in its down (dwelled) position;

Figure 2 is the partial cross-sectional view of the actuator mechanism of the dispenser of Figures 1A-1D;

20 Figure 3 is a partial cross-sectional view of the mechanism of Figure 2 upon activation caused by inhalation; and

Figure 4 is a partial cross-sectional view of the actuator mechanism of Figure 2.

Detailed Description of the Preferred Embodiment

25 Referring now more particularly to the Figures, there is shown a breath activated device or metered dose inhaler, sometimes referred to as the dispenser, generally designated by the reference numeral 70.

The dispenser 70 includes a housing 72 for containing an aerosol container or canister 73, containing a medication, e.g. beclomethasone dipropionate, cortisone, epinephrine, erythromycin, etc., or a placebo and liquid propellant, e.g. 1,1,1,2-tetrafluoroethane (HFC-134a), 1,1,1,2,3,3,3-heptafluoropropane (HFC-227), or other propellant suitable for purpose. The housing 72 may be fabricated from a metal, e.g. aluminum, etc., or a plastic, e.g. ABS, polypropylene, polyethylene, etc. or other material suitable for purpose. Where a disposable inhalation device 70 is contemplated, the housing 72 is preferably molded of a plastic material. The canister 73 is a conventional pressurized container, and may also be fabricated from a metal, such as, aluminum, etc., or plastic, e.g. ABS, polypropylene, etc., or other material. If the dispenser 70 is intended to be disposable, plastic material is preferred.

The canister 73 has at one end a metering dispensing valve 74 for dispensing a dose of medication from the canister 73 through a hollow valve stem 76, to a nozzle 77 which has an exit opening 78 at its far end which communicates (optionally) with a conventional spacer (not shown). The valve stem 76 is normally "charged" in its extended position (Figure 1A) but when depressed (Figure 1D) will discharge to dispense an aerosol stream of medication from the canister 73 via valve 76. In this regard, the valve 74 has an

internal spring (not shown) which biases the stem 76 so that it is extended before discharging of the device 70 and which returns to its original position after discharging.

5 The nozzle 77, typically fabricated from polyethylene, polypropylene, etc., is centrally located in alignment with the aperture or opening 75 of the valve stem 76 where upon depression of the stem 76 a metered quantity or dose of the
10 medication is dispensed from the container 73 through the valve 74.

In operation, the medication is dispensed from the canister 73 through the valve 74 through the stem 76 into the nozzle 77 through its exit 78 into
15 a mouthpiece 79. The mouthpiece may be integrally formed in or separately attached to the end of the housing 72. The mouthpiece 79 has an opening 81 which is placed into a patient's mouth (not shown) for treatment with the medication. The dispensed
20 dose of medication passes through the nozzle 77, optionally into a spacer (not shown), into the mouthpiece 79 and out the opening 81 into the patient's mouth and lungs.

Any conventional nozzle 77 can be employed
25 depending upon the aerosol spray desired. A particular nozzle may be selected by the skilled artisan to produce a particular shape or plume, including the acceleration of the medication aerosol spray.

Preferably the vortex nozzle described in U.S. Application Serial Number 60/135,056, filed on May 20, 1999, incorporated hereinto by reference in its entirety, may be employed. Also, the metered dose counting features as set forth in the aforementioned patents and applications may also be included in the present invention as would be readily apparent to those skilled in the art.

The housing 72 comprises a chamber 84 into which the canister 73 is inserted with its stem 76 down. The housing 72 includes a dwell chamber body 82 which may be fabricated from LDPE, polypropylene or other material suitable for purpose. The dwell chamber body 82 receives the container 73 with the valve 74 and the stem 76 in communication with an aperture orifice 83. The orifice 83 serves to direct the medication travelling from the stem 76 through the nozzle 77 and its exit 78, optionally through the spacer (not shown), and to the mouthpiece opening 81.

Referring to Figure 1A, the dwell chamber body 82 is contoured to slideably fit and hold the valve 74, the stem 76 and includes an upper circumferential lip 86. The dispenser 70 is armed or cocked by a handle (not shown). This arms the actuator mechanism or means 90 (see Figure 3), the stem 76 is thereby depressed whereby the metered dose from the valve is dispensed or released. The dwell chamber body 82, in association with the actuator mechanism 90, serve to keep the container

73, valve 74 and stem 76 in a depressed position for a desired period of time, e.g. about 10 milliseconds to about 4 seconds. This ensures adequate time for the metering valve to release the medication. When the valve stem 76 returns to its extended position the metering valve is charged with another dose and is then ready for the next use.

In its dwelled position (Figure 1D), the dwell chamber body 82 engages the surface 80 of the canister 73 a distance from annular surface 88 of the dwell chamber body 82 to form an upper dwell chamber 91 having a first dimension and a lower dwell chamber 94 as well having a smaller second dimension.

The actuator mechanism 90 (Figure 2), causes the movement of the canister 73 from a first or not dwelled position as shown in Figures 1A-1C to a second or dwelled position shown in Figure 1D. In the dwelled position, the canister 73 bottoms out in the lower dwell chamber 94 causing the medication to be discharged during inhalation by the patient. To prevent any escape of the medication upwardly out of the dwell chamber body 82, and to accomodate variation in size of stems 76, the dispenser 70 may include a soft seal gasket (not shown) located in the dwell chamber body 82.

The upper dwell chamber 91 and the lower dwell chamber 94 in the undwelled position contain air which is allowed to escape upon depressing the

canister 73, via T-shaped vent 95. Through the engagement of the valve surfaces 74 with the dwell chambers 91 and 94, there is a sliding relationship which however retards the return of the canister 73 to the undwelled position due to the engagement therebetween when the canister is depressed. This is the result of a vacuum formed in the chambers when the air is forced out. The vent 95 between the first dwell chamber 91 and the second dwell chamber 94 extend to the outside of dwell chamber body 82 to expel the air upon activation of the dispenser 70. Additionally, the walls 92 of the upper chamber 91 are of thin cross section which may expand and allow a certain amount of air to escape through annular space 126. An elastomeric flap or one way check valve 97, typically fabricated from silicone, etc. permits air passing through the vents 95 and out of the dwell chamber body 82.

In addition, the first dwell chamber 91 acts as a sort of dash pot to cushion or dampen the movement of the canister 73 and its elements to avoid shock thereto by the activation by means 90.

Turning now briefly to the embodiment shown in Figures 1B-1D, this is the same as that shown in Figures 1A, 2-4, with the exception of the dwell chamber body 82' (corresponding but differently constructed parts being designated with a prime). In this embodiment there is provided a venting mechanism 95' comprising a series of radial vent

tubes 130 for venting dwell chamber 91 and a tubular vent 132 for venting dwell chamber 94. Positioned about the outside of the dwell chamber body 82' is an elastomeric sleeve valve 93. This sleeve valve 93 acts as a one way check valve and is sufficiently flexible so as to expand outward providing a path for air to escape from chambers 91 and 94 when the canister 73 is being pushed down into the dwell position. Subsequent to this, sleeve valve 93 returns to its original position sealing off the vents thereby causing a vacuum resistance which prevents the canister from returning to its rest position thereby maintaining the dwell period.

Turning now more particularly to the actuator mechanism 90, formed within the housing 72 is a suction tube 98 which communicates the mouthpiece 79 with a diaphragm chamber 99 of the actuator mechanism 90 (Figure 2). The tube 98 provides air to the user of the dispenser 70 when the dispenser 70 is in position to be activated by the actuator mechanism 90. The actuator mechanism 90 comprises an actuator housing 101 which is pivotably affixed to the top of the housing 72 by means of a pivot pin 102.

Formed within the actuator housing 101 is the diaphragm chamber 99 having the suction tube 98 communicating therewith from the mouthpiece 79. The upper surface of chamber 99 is defined by means of an elastomeric diaphragm 103 whereas the lower

surface of the chamber 99 is defined by a canister actuator 104 which serves to move the canister 73 to the dwell position upon the inhalation of the person using the dispenser 70. The diaphragm 103 is movably affixed within housing 101 contiguous to a second latch means 106. The actuator 104 is vertically moveable within housing 101 within a slotted member guide 105. The actuator upon activation moves vertically down the housing 72 guided by means of the slotted guide member 105 to sequentially (a) contact and move the canister 73 into the dwell position; (b) dispense the medication from the valve 74; (c) reload the valve 74 with the next dose of medication; and (d) return the dispenser 70 to its undwell position awaiting activation by another inhalation.

The second latch means 106, upon cocking of the dispenser 70 by the handle (not shown), latches the actuator housing 101 until the device 70 is activated by inhalation of the patient being treated. The canister actuator 104 additionally overlays the bottom surface 107 of the inverted canister 73.

The diaphragm 103 is an elastic member, typically of circular configuration. The diaphragm 103 preferably has an elasticity suitable for permitting deformation in the presence of an inhalation through the suction tube 98. The diaphragm 103 is typically fabricated from a silicone rubber, neoprene, buna rubber, etc. and is

of thin cross sectional area. Diaphragm 103 is molded with an internal feature designed to engage a lip on actuator housing 101 as shown in Figure 4.

As indicated, referring to Figures 1A and 2, when a patient employs the dispenser 70 and inhales through the mouthpiece 79 and thus through suction tube 98, a negative pressure is created beneath diaphragm 103 in chamber 99. As a result, the diaphragm 103 is then displaced towards surface 107 of the canister 73 due to this negative pressure resulting in the movement of the actuator means 104 downward against the canister 73 and the ultimate dispensing of the medication.

The actuator housing 101, diaphragm 103 and chamber 99 may be fabricated from any material suitable for purpose. Note the dimensions and characteristics of the diaphragm 103 may be adjusted or modified (e.g. thickness, flexibility, or type of material) to allow for more or less suction to activate the device. The housing 101 has affixed to it by any conventional means the handle (not shown) which is vertically oriented. Upon depressing the handle (not shown), the housing 101 is locked in place by the second latch means 106 and the actuator mechanism 90 is in the armed position where an actuation or activation linkage arrangement of the actuator mechanism 90 is ready. Referring to Figure 2, the actuation linkage arrangement comprises a drive arm 108 and a first latch means 109. The drive arm 108 and the latch

109 form a two link linkage system which is
destined to be acted upon by a spring 111 via the
drive arm 108. The bottom of the drive arm 108 is
pivotably attached to the actuator housing 101 by
5 means of a pivot pin 112. The top of the drive arm
108 is pivotably connected or attached to the top
of the latch means 109 by means of a pivot pin 113.
The bottom of the latch means 109 is pivotably
connected to the housing 101 by means of a pivot
10 pin 115 and is capable of moving horizontally
within a slot 116 of housing 101 upon actuation of
the dispenser 70.

A drive member 114 is pivotably attached at
its top portion to the drive arm 108 by means of
15 the pivot pin 113 and its bottom portion is
pivotably attached to the canister actuator 104 by
means of a pivot pin 121. When the dispenser 70 is
fired by the actuator means 90, the drive arm 108
has a rotational force about pin 112 applied to it
20 by the spring 111 whereby a translational force is
applied by the drive member 114 to the canister
actuator 104 driving it within the slot of the
slotted guide member 105 against the canister 73.

As illustrated in Figure 3, upon actuation of
25 the dispenser 70 the canister actuator 104 slides
away from the remainder of the diaphragm chamber
99, to permit air to enter into the device 70. In
this regard, also as illustrated in Figure 3, the
housing 101 which is pivotably attached to the
30 housing 72 by pin 102, upon activation of the

dispenser 70, is released from the second latch means 106 and pivots up and away from the moving canister actuator 104 to also thereby permit air to enter into the fired device 70 after the canister 73 and valve 74 bottoms out. As previously indicated, the actuator 104 is in an adjacent or contiguous relationship with surface 107 of the chamber 99 prior to the activation of the dispenser 70.

Referring to Figure 1A, the canister actuator 104, upon activation of the dispenser 70 by mechanism 90, is destined to contact the bottom surface 107 of the canister 73 and move the canister 73 and the valve 74 into and through dwell chamber 91 and into chamber 94 where the stem 76 is fully inserted into the nozzle 77. The stem 76 bottoms out to dispense the dose of medication through the valve.

When the device 70 is armed or cocked by means of the handle (not shown), a portion 122 of the first latch means 109 is prevented from moving by a keeper 119 which is pivotally attached by means of a pivot pin 121 to a diaphragm linkage 123 which is affixed, typically at the center, to the diaphragm 103 and is used to release the first latch means 109 upon movement of the diaphragm 103 which occurs upon inhalation by the patient being treated. The keeper 119, the diaphragm linkage 123 and the fixed diaphragm 103 all prevent portion 122 of the first

latch means 109 from moving when the dispenser 70 is cocked or armed; which arming is accomplished by pressing the movable handle (not shown).

When the handle is pressed, it engages arming member 117 which pushes, via pin 115, portion 122 of the first latch means 109 towards the drive pivot point at pin 115. Then the two linkage system (drive arm 108 linked to the first latch means 109) folds around the common pivot point at the second pivot pin 113 until portion 122 of the latch 109 and the keeper 119 lock together. The second latching means 106 is engaged upon arming with the handle. The moveable handle (not shown) is then free to return to an extended position where further manipulation of the handle will not cause any action.

Referring to Figures 1A and 3, in use, the dispenser 70, armed by movement of the handle (not shown) and held in an upright position, a patient inhales through opening 81 of the mouthpiece 79. The inhalation creates a negative pressure along a flow path from the opening 81, through the suction tube 98 into the diaphragm chamber 99. The diaphragm 103 is acted upon by the negative pressure whereby it is deflected towards the canister 73 pulling on the keeper 119 via the diaphragm linkage 123 thereby moving the bottom portion 122 of the first latch means 109 along the slot 116 of the guide member 117 to release portion 122 of the latch means 109 from the keeper 119.

This pulling action, which is vertical from the first latch means 109, allows latch linkage horizontal movement which translates perpendicularly to the movement of the diaphragm 103. This translation is caused by the spring 111 acting on the drive arm 108. The spring 111 urges the drive arm 108 to rotate about its pivot point at pivot pin 112 within the actuator housing 101 whereby portion 122 of the first latch means 109 slides along slot 116.

The rotation of the drive arm 108 translates to a linear, downward moving force to the drive member 114 driving the member 114 towards the canister 73 by means of the pin 121 along the slot of slotted guide member 105 contained therein to move the canister actuator 104 into contact with the surface 107 of the canister 73 and drive the canister 73 and its elements 74 and 76 into chambers 91 and 94 to deliver a metered dose to the patient.

When the canister 73 reaches the bottom of the lower dwell chamber 94, the stem 76 bottoms out and is completely compressed. At this juncture, the canister 73 is held in place by both vacuum and friction for a desired period of time which dictates that the aerosol dose of the medication is fully delivered to the patient and that the valve 74 is fully re-filled or replenished with the requisite dose of the medication, e.g. typically about 10 milliseconds to about 4 seconds. The

internal valve spring (not shown) in the valve 74 of the canister 73 will slowly overcome the vacuum and friction forces after the requisite dwell time, e.g., 100 milliseconds, and return the valve stem
5 76, the valve 74 and the canister 70 to their original position.

It should be noted that variations to the actuator means 90 are envisioned. For example, spring 111 can be positioned beneath diaphragm 103
10 to provide an axial transitional force downward on canister actuator 104 upon the triggering of the device. Appropriate adjustment of the linkage arrangement can be made to accommodate the position of the spring in this regard. Other variations
15 should be apparent to those skilled in the art.

Thus by the present invention its objects and advantages are realized and although preferred embodiments have been disclosed and described in detail herein, its scope should not be limited
20 thereby rather its scope should be determined by that of the appended claims.

What Is Claimed Is:

1. An inhalation activated dispenser, which comprises:

5 (a) a housing means for containing an aerosol medication containing canister and having an inhalation means for a patient to inhale a metered dose of said medication contained in said canister;

 (b) said canister movably contained within
10 said housing means having a means for dispensing by spraying said metered dose;

 (c) a means in cooperation with said canister which upon inhalation by said patient through said inhalation means moves said canister to activate
15 the dispenser to release a spray of metered dose therefrom; and

 (d) a dwell means within said housing means for maintaining said canister for a sufficient period of time to replenish in said dispensing
20 means a metered dose of said medication.

2. The dispenser of claim 1, which further comprises a means for removing air from the said dwell means prior to said release of spray.

25

3. The dispenser of claim 1, wherein said dwell means includes a first dwell chamber engageable with the canister for maintaining the canister for said sufficient period of time.

30 4. The dispenser of claim 3, wherein said dwell means further comprises a second dwell chamber.

5. The dispenser of claim 4, which includes means for venting said chambers.

5 6. The dispenser of claim 5, wherein said venting means includes a one way check valve.

7. The dispenser of claim 5, wherein said venting means includes an elastomeric sleeve valve.

10

8. An inhalation activatable dispenser for use with an aerosol container having a valve for dispensing aerosol from an outlet in the container, the valve having a hollow stem which is moveable
15 relative to the container between an extended closed position and a compressed discharge position of the valve, upon the inhalation of a patient, which comprises:

(a) a housing, having a mouthpiece and an air
20 passage therethrough terminating at said mouthpiece, for receiving and moveably retaining the aerosol container;

(b) a nozzle seat within said housing with a means to receive the stem and a through orifice
25 communicating between the stem and said air passage;

(c) an activator means for activating the dispenser to dispense said metered dose, of the aerosol, comprising a latch means having parts
30 moveable between an engaged position and a release

position for preventing when said parts are in said engaged position, the movement of the container and said nozzle seat toward each other upon the application of a force to bias the container and
5 said nozzle seat toward each other and for affording, upon the inhalation of the patient through said mouthpiece and said air passageway when said parts are in said release position, movement of the container and said nozzle seat
10 toward each other in response to said force to move the stem to its compressed discharge position;

(d) a dwell means for establishing a dwell time period in which the stem is in its compressed discharge position when said latch means is in its
15 release position.

9. The dispenser as defined in claim 8, wherein said activator means comprises,

a container actuator, which defines the bottom
20 of a chamber, which is connected to said mouthpiece by said inhalation means, said actuator being in contact with the container and, moves the container toward said nozzle seat when said latch means is in its release position; and

25 a diaphragm, which defines the top of said chamber, which is pivotably affixed to a linkage means which cooperates with said latch means, where said diaphragm upon the inhalation by the patient moves said latch means into its release position to

cause said container actuator to move the container toward said nozzle seat.

10. The dispenser as defined in claim 9, wherein
5 said linkage means comprises,

a latch cooperating with a keeper which is pivotably attached to said housing and which engages said latch, said keeper being pivotably attached to said diaphragm for movement with said
10 diaphragm to cause release of said latch from said keeper.

11. The dispenser as defined in claim 10 which further comprises a drive member pivotably attached
15 to and moveably by said linkage means for urging a force to said container actuator to move the container.

12. The dispenser as defined in claim 11 which
20 further comprises a drive arm pivotably attached to said drive member where said drive arm urges said force to said drive member.

13. The dispenser of claim 8 which further
25 comprises a means for removing air from said dwell means prior to said dwell time period.

14. The dispenser of claim 13, wherein said dwell means includes a first dwell chamber engageable

with the canister for maintaining the canister for said sufficient period of time.

15. The dispenser of claim 14, wherein said dwell
5 means further comprises a second dwell chamber.

16. The dispenser of claim 15, which includes means for venting said chambers.

10 17. The dispenser of claim 16, wherein said venting means includes a one way check valve.

18. The dispenser of claim 16, wherein said venting means includes an elastomeric sleeve valve.

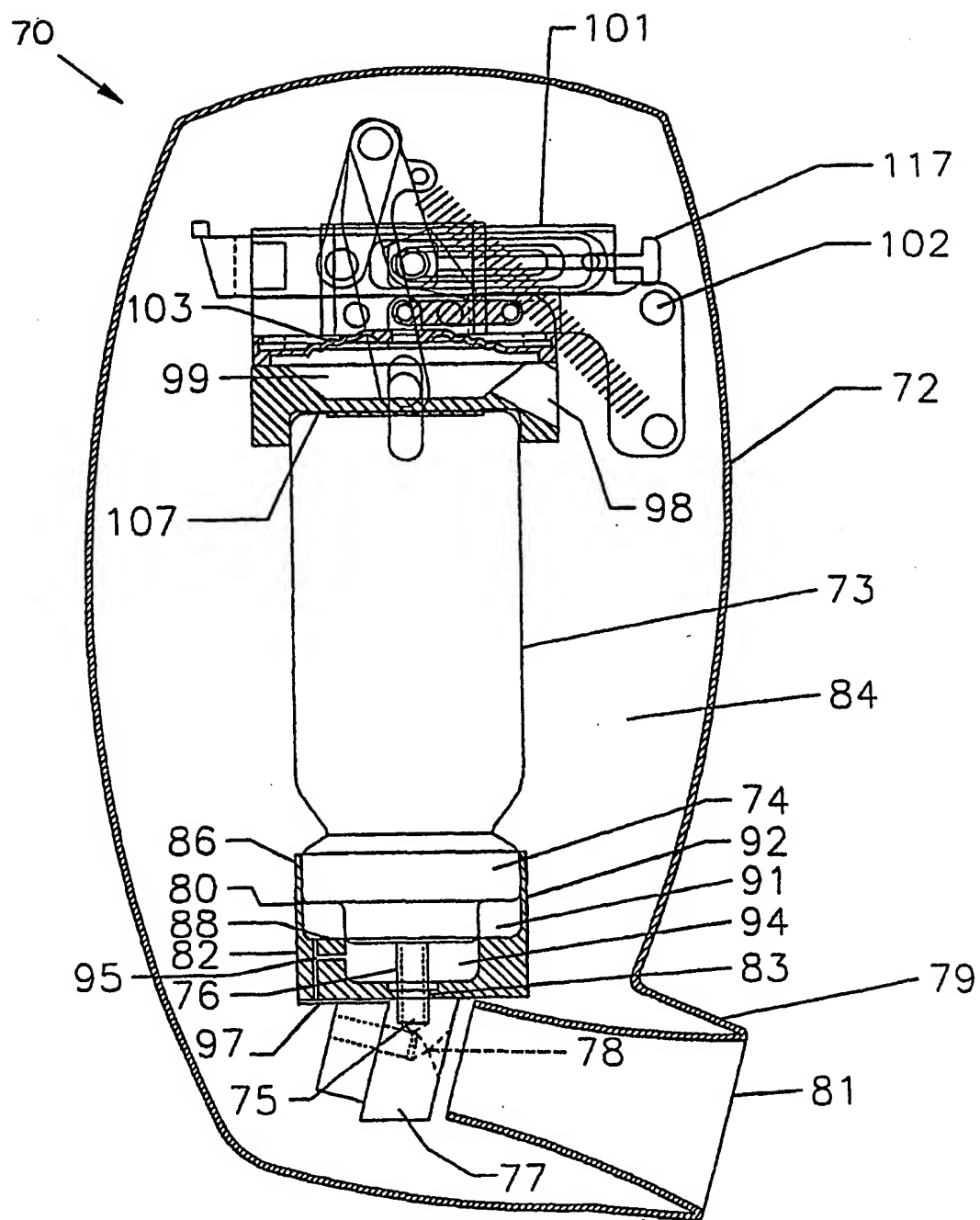


FIG. 1A

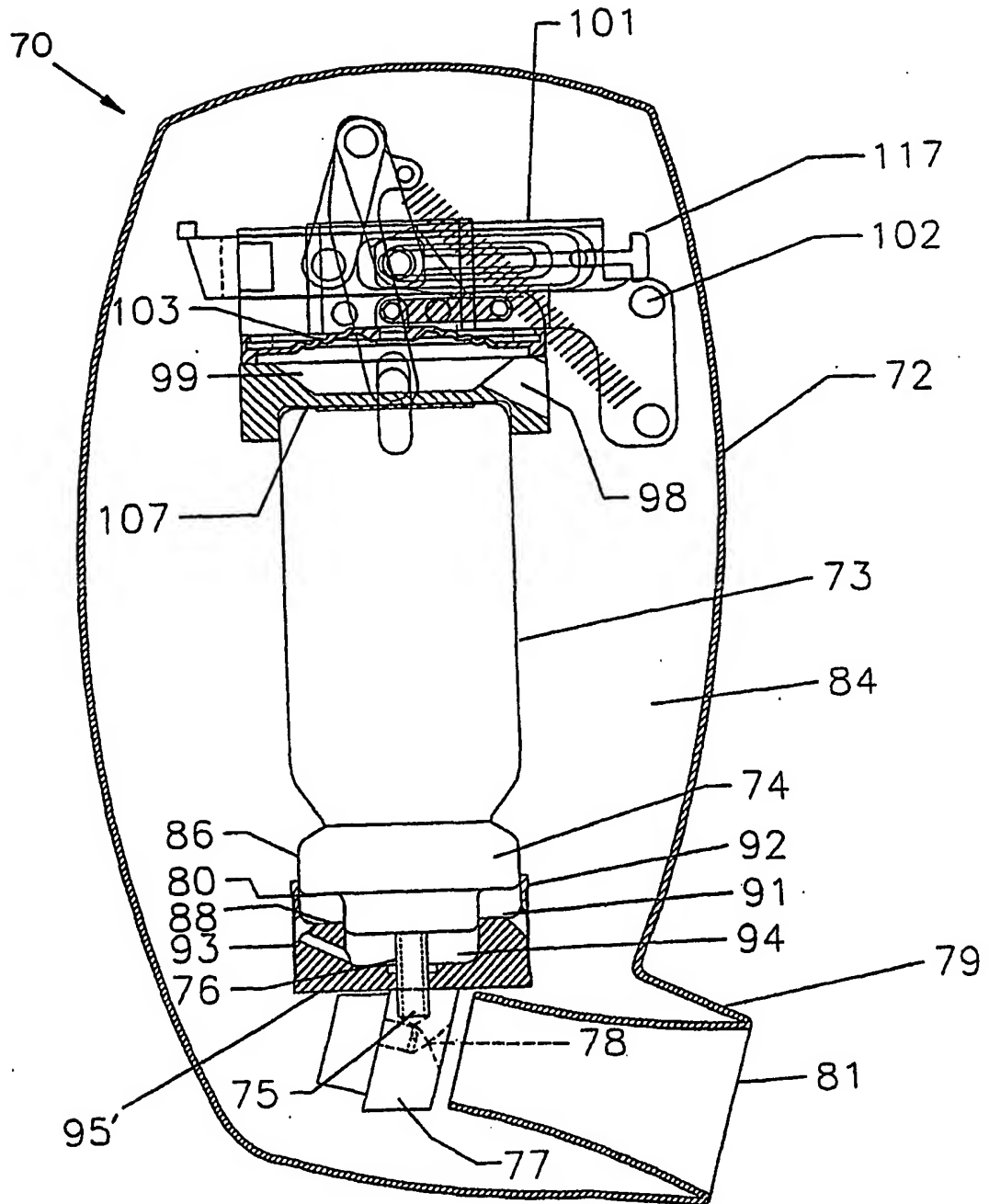


FIG. 1B

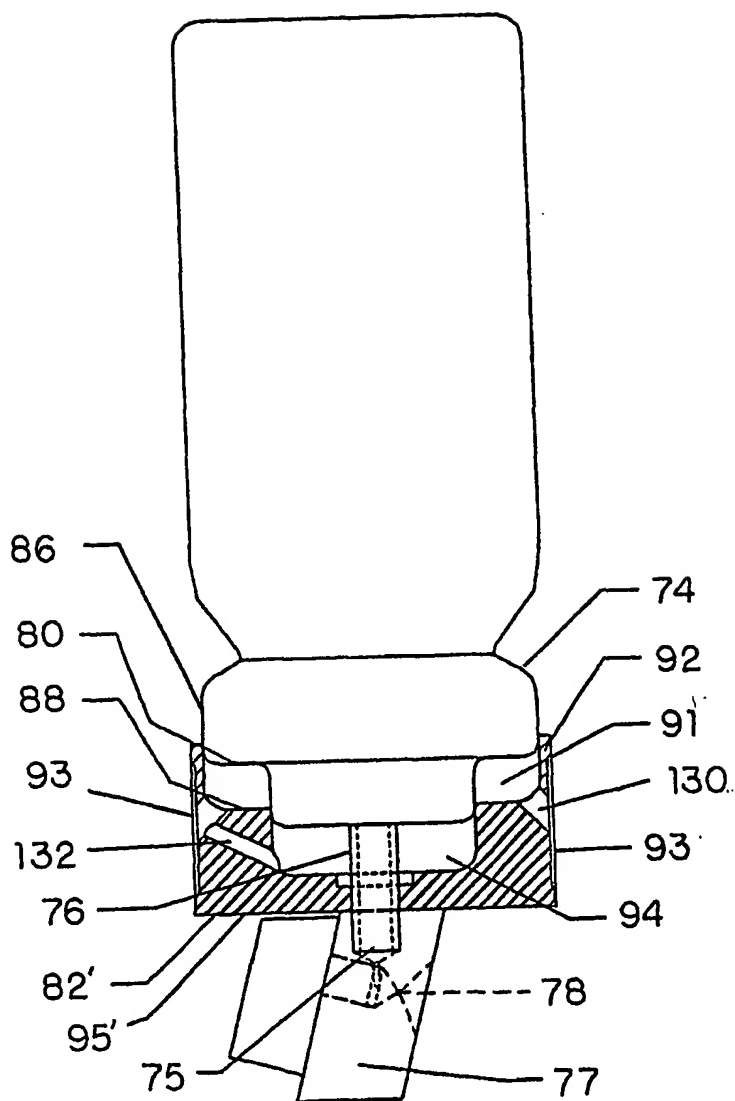


FIG. 1C

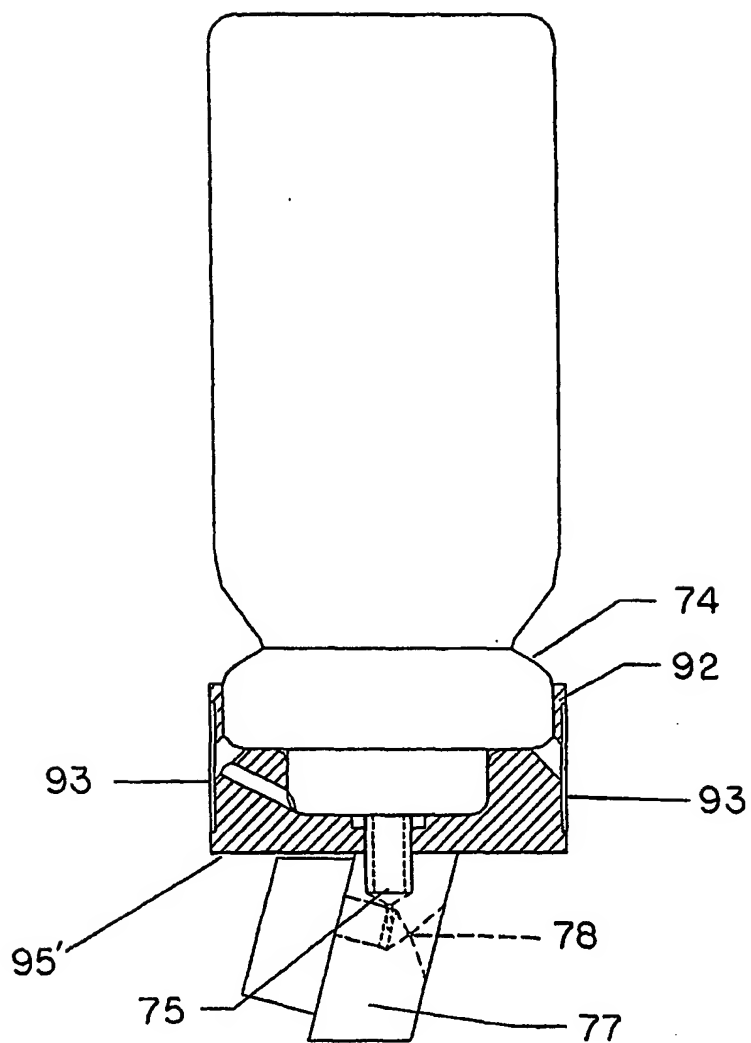


FIG. 1D

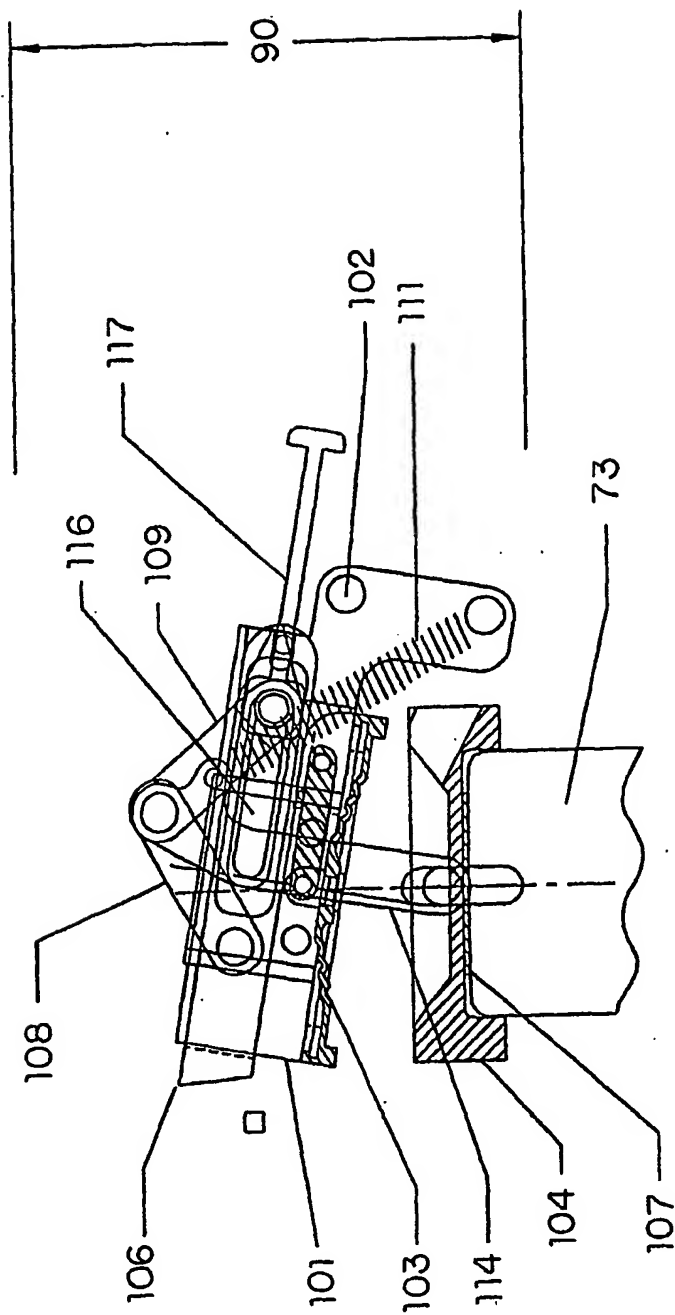


FIG. 3

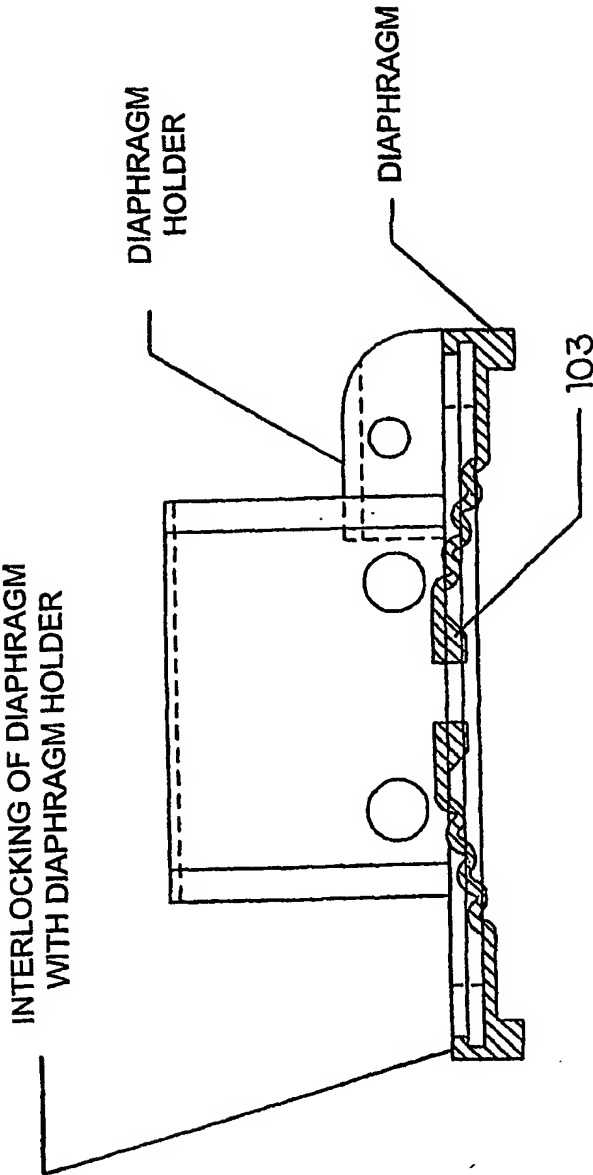


FIG. 4

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 September 2001 (27.09.2001)

PCT

(10) International Publication Number
WO 01/70319 A3

(51) International Patent Classification⁷: A61M 15/00,
B65D 83/14

11309 Derby Lane, Raleigh, NC 27613 (US). WAKE-
FIELD, Keith; 297A Winston Road, Clayton, NC 27520
(US).

(21) International Application Number: PCT/US01/07202

(22) International Filing Date: 7 March 2001 (07.03.2001)

(74) Agents: SANTUCCI, Ronald, R. et al.: Frommer
Lawrence & Haug LLP, 745 Fifth Avenue, New York, NY
10151 (US).

(25) Filing Language: English

(26) Publication Language: English

(81) Designated States (*national*): AU, CA, JP.

(30) Priority Data:
09/531,732 21 March 2000 (21.03.2000) US

(84) Designated States (*regional*): European patent (AT, BE,
CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC,
NL, PT, SE, TR).

(71) Applicant: IEP PHARMACEUTICAL DEVICES,
INC. [US/US]; 6320 Angus Drive, Raleigh, NC 27617
(US).

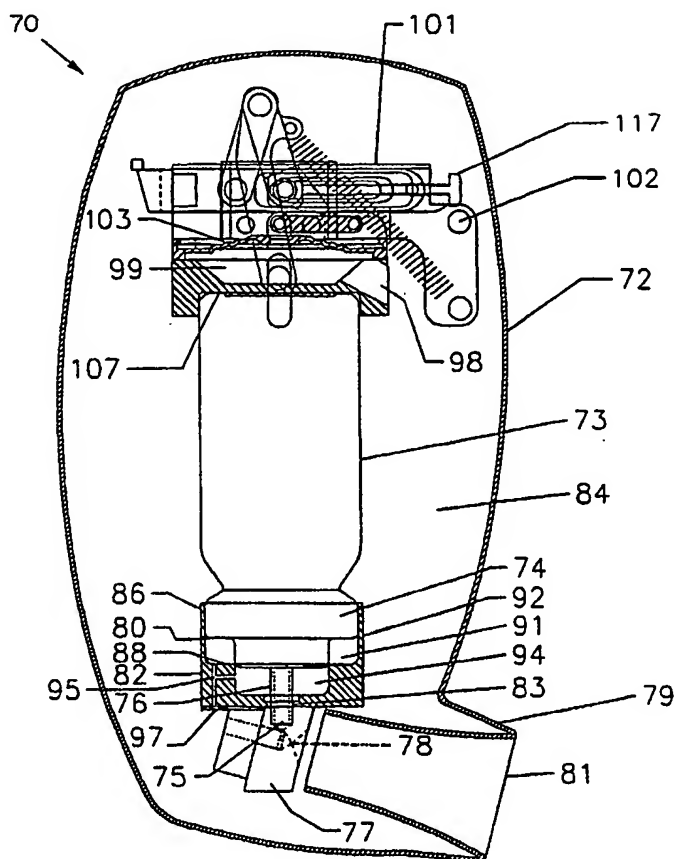
Published:
— with international search report

(72) Inventors: GENOVA, Perry, A.; P.O. Box 16036, Chapel
Hill, NC 27516 (US). WILLIAMS, Robert, C., III;

(88) Date of publication of the international search report:
28 February 2002

[Continued on next page]

(54) Title: AN INHALATION ACTUATED DEVICE



(57) Abstract: An inhalation activated device or dispenser is disclosed. In particular, the dispenser comprises a housing for containing an aerosol canister containing a medication wherein the canister is moveably contained in the housing upon inhalation by the patient whereby a metered dose of a spray is initiated and a controlled period of time is established by a dwell means.

WO 01/70319 A3



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No.

PLI/US 01/07202

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00 B65D83/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 06091 A (INNOVATIVE DEVICES LLC) 11 February 1999 (1999-02-11) page 11, paragraph 2 -page 12, paragraph 1 ----	1,8
X	EP 0 490 797 A (TENAX CORP) 17 June 1992 (1992-06-17) column 7, line 19 -column 8, line 1; figures 1-5 ----	1,8
A	WO 93 24167 A (NORTON HEALTHCARE LTD ;HOLROYD MICHAEL JOHN (GB)) 9 December 1993 (1993-12-09) abstract; figures -----	9

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

14 November 2001

Date of mailing of the international search report

21/11/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Villeneuve, J-M

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/07202

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9906091	A	11-02-1999	US 5826571 A	27-10-1998
			WO 9906091 A1	11-02-1999
			AU 732869 B2	03-05-2001
			AU 3743297 A	22-02-1999
			EP 1019125 A1	19-07-2000
			JP 2001511401 T	14-08-2001
EP 0490797	A	17-06-1992	US 5217004 A	08-06-1993
			AT 125715 T	15-08-1995
			AU 653562 B2	06-10-1994
			AU 8961291 A	18-06-1992
			CA 2057419 A1	14-06-1992
			DE 69111771 D1	07-09-1995
			DE 69111771 T2	07-12-1995
			DK 490797 T3	02-01-1996
			EP 0490797 A1	17-06-1992
			ES 2075395 T3	01-10-1995
			FI 915848 A	14-06-1992
			HU 211361 B	28-11-1995
			IE 914361 A1	17-06-1992
			IL 100201 A	18-06-1996
			JP 1993668 C	22-11-1995
			JP 4307069 A	29-10-1992
			JP 6085802 B	02-11-1994
			KR 164224 B1	15-01-1999
			MX 9102552 A1	01-06-1992
			NO 303621 B1	10-08-1998
			NZ 240932 A	25-02-1994
			PT 99783 A , B	30-11-1993
			ZA 9109735 A	30-09-1992
WO 9324167	A	09-12-1993	AU 4083993 A	30-12-1993
			CN 1079167 A	08-12-1993
			WO 9324167 A1	09-12-1993
			TR 26757 A	15-05-1995
			ZA 9303639 A	20-12-1993